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FORM**

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Application Number

10/633,808

Filing Date

08/04/2003

First Named Inventor

Alexander V. Sokoloff, et al.,

Group Art Unit

Examiner Name

Total Number of Pages in This Submission

211

Attorney Docket Number

14.04.1

ENCLOSURES (check all that apply)☐

Fee Transmittal Form

☐

Fee Attached

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Amendment / Reply

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After Final

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Affidavits/declaration(s)

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Extension of Time Request

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Express Abandonment Request

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Information Disclosure Statement

☐

Certified Copy of Priority Document(s)

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Incomplete Application☐Response to Missing Parts
under 37 CFR 1.52 or 1.53☐Assignment Papers
(for an Application)☐

Drawing(s)

☐

Licensing-related Papers

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Petition

☐Petition to Convert to a
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Terminal Disclaimer

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Request for Refund

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CD, Number of CD(s) _____

☐After Allowance Communication
to Group☐Appeal Communication to Board
of Appeals and Interferences☐Appeal Communication to Group
(Appeal Notice, Brief, Reply Brief)☐

Proprietary Information

☐

Status Letter

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Remarks

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Alexander V. Sokoloff,)
So Wong, Jon A. Wolff,)
Sean D. Monahan, James Ludtke)
Lori Higgs, Darren Wakefield,)
Magdolna G. Sebestyén)
Serial No.: 10/633,808)
Filed: 08/04/2003)
Group Art Unit:)

For: **Compounds for Targeting Hepatocytes**

INFORMATIONAL STATEMENT

Commissioner of Patents
P.O. BOX 1450
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 C.F.R. 1.56, applicant hereby calls to the attention of the Patent and Trademark Office the publications listed on the attached PTO 1449. This information statement supplements the previously filed information statement.

REFERENCES CITED

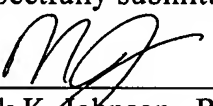
- Biessen EAL, et al. "Ligand size is a major determinant of high-affinity binding of fucose- and galactose-exposing (lipo)proteins by the hepatic fucose receptor." *Biochem J* 1994 Vol. 299 pp. 291-296.
- Bijsterbosch MK, et al "Native and modified lipoproteins as drug delivery systems. *Advanced Drug Delivery Reviews* 1990 Vol. 5 pp. 213-251.
- Chiou HC, et al. "Gene therapy strategies for the treatment of chronic viral hepatitis. *Expert Opinion on Biological Therapy* 2001 Vol. 1 pp. 629-639.
- Fiume L, et al. "Inhibition of hepatitis viral replication by vidarabine monophosphate conjugated with lactasaminated serum albumin. *Lancet* 1988 Vol. 2 pp. 13-15.
- Fiume L, et al. "The pathogenesis of vacuoles produced in rat and mouse liver cells by a conjugate of adenine arabinoside monophosphate with lactosaminated albumin. *J Hepatology* 1992 Vol. 15 pp. 314-322.

- Furumoto K, et al. "Biliary excretion of polystyrene microspheres depends on the type of receptor-mediated uptake in rat liver. *Biochimica et Biophysica Acta* 2001 Vol. 1526 pp. 221-226.
- Goldberg J, et al. "Erythropoietin mimetics derived from solution phase combinatorial libraries. *J Amer Chem Soc* 2002 Vol. 124 pp. 544-555.
- Groman EV, et al. "Arabinogalactan for hepatic drug delivery. *Bioconj Chem* 1994 Vol. 5 pp. 547-556.
- High KA. "Gene transfer as an approach to treating hemophilia. *Circulation Research* 2001 Vol. 88 pp. 137-144.
- Koide A, et al. "The fibronectin type III domain as a scaffold for novel binding proteins. *Journal of Molecular Biology* 1998 Vol. 284 pp. 1141-1151.
- Lee YC, et al. "Binding of synthetic oligosaccharides to the hepatic gal/GalNAc lectin. *J Biol Chem* 1983 Vol. 258 pp. 199-202.
- Meiher DKF, et al. "Drug targeting systems for antiviral agents: options and limitations. *Antiviral Research* 1992 Vol. 18 pp. 215-258.
- Nord K, et al. "Binding proteins selected from combinatorial libraries of an alpha-helical bacterial receptor domain. *Nature Biotechnology* 1997 Vol. 15 pp. 772-777.
- Nord K, et al. "A combinatorial library of an alpha-helical bacterial receptor domain. *Protein Engineering* 1995 Vol. 8 pp. 601-608.
- Okuno K, et al. "Hepatic immunopotentiality by galactose-entrapped liposomal IL-2 compound in the treatment of liver metastases. *Surg Today* 1998 Vol. 28 pp. 64-69.
- Rensen PC, et al. "Determination of the upper size limit for uptake and processing of ligands by the asialoglycoprotein receptor on hepatocytes *in vitro* and *in vivo*. *Journal of Biological Chemistry* 2001 Vol. 276 pp. 37577-37584.
- Rogers JC, et al. "Hepatic uptake of proteins coupled to fetuin glycoprotein. *Biochem Biophys Res Comm* 1971 Vol. 45 pp. 622-629.
- Schlepper-Schafer J, et al. "Endocytosis via galactose receptors *in vivo*. Ligand size directs uptake by hepatocytes and/or liver macrophages. *Experimental Cell Research* 1986 Vol. 165 pp. 494-506.
- Severin E, et al. "Flow cytometric analysis of mouse hepatocyte ploidy. II. The development of polyploidy pattern in four mice strains with different life spans. *Cell & Tissue Research* 1984 Vol. 238 pp. 649-652.
- Shimada K, et al. "Biodistribution of liposomes containing synthetic galactose-terminated diacylglycerol-poly(ethylene)glycols. *Biochim Biophys Acta* 1997 Vol. 1326 pp. 329-341.
- Sokoloff AV, et al. "Specific recognition of protein carboxy-terminal sequences by natural IgM antibodies in normal serum. *Molecular Therapy* 2001 Vol. 3 pp. 821-830.
- Sokoloff AV, et al. "The interactions of peptides with the innate immune system studied with use of T7 phage peptide display. *Molecular Therapy* 2000 Vol. 2 pp. 131-139.

- Sofoloff AV, et al. "A new peptide ligand that targets particles and heterologous proteins to hepatocytes in vivo." *Molecular Therapy* 2003 Vol. 8 No. 6 pp. 867-872.
- Steven AC, et al. "Molecular substructure of a viral receptor-recognition protein. The gp17 tail-fiber of bacteriophage T7. *Journal of Molecular Biology* 1988 Vol. 200 pp. 351-365.
- Studier FW "The genetics and physiology of bacteriophage T7. *Virology* 1969 Vol. 39 pp. 562-574.
- Tomlinson E "Theory and practice of site-specific drug delivery. *Advance Drug Delivery Reviews* 1987 Vol. 1 pp. 87-98.
- van Berkel JC, et al. "The effect of a water-soluble tris-galactoside-terminated cholesterol derivative on the fate of low density lipoproteins and liposomes. *J Biol Chem* 1985 Vol. 260 pp. 2694-2699.
- Vyas SP, et al. "Endogenous carriers and ligands in non-immunogenic site-specific drug delivery. *Advanced Drug Delivery Reviews* 2000 Vol. 43 pp. 101-164.
- Weglarz TC, et al. "Hepatocyte transplantation into diseased mouse liver. Kinetics of parenchymal repopulation and identification of the proliferative capacity of tetraploid and octaploid hepatocytes. *American Journal of Pathology* 2000 Vol. 157 pp. 1963-1974.
- Wu J, et al. "Targeting hepatocytes for drug and gene delivery pp. emerging novel approaches and applications. *Frontiers in Bioscience* 2002 Vol. 7 pp. 717-725.

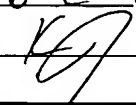
Applicant respectfully requests that these publications be expressly considered during the prosecution of this application and made of record herein and appear among the 'References Cited' on any patent to issue herefrom.

Respectfully submitted,

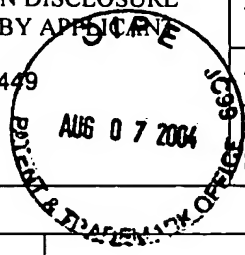

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8-2-04



INFORMATION DISCLOSURE STATEMENT BY APPLICANT FORM PTO-1449	Attorney Docket No.: Mirus.014.04.1	Serial No.: 10/633,808
	Applicant: Alexander V. Sokoloff, So Wong, Jon A. Wolff, Sean D. Monahan, James Ludtke, Lori Higgs, Darren Wakefield, Magdolna G. Sebestyén	Group:
		Examiner:



U.S. PATENT DOCUMENTS

Exmnr Intl	Seq	Patent Number	Issue Date	Patentee	Class	Sub Class	Filing Date

FOREIGN PATENT OR PUBLISHED FOREIGN PATENT APPLICATION

		Document Number	Publication Date	Country or Patent Office	Class	Sub Class	Transl.	
							yes	no

OTHER DOCUMENTS (Including Author, Title, Date Pertinent Pages, etc.)

		Biessen EAL, et al. "Ligand size is a major determinant of high-affinity binding of fucose- and galactose-exposing (lipo)proteins by the hepatic fucose receptor." <i>Biochem J</i> 1994 Vol. 299 pp. 291-296.
		Bijsterbosch MK, et al "Native and modified lipoproteins as drug delivery systems. <i>Advanced Drug Delivery Reviews</i> 1990 Vol. 5 pp. 213-251.
		Chiou HC, et al. "Gene therapy strategies for the treatment of chronic viral hepatitis. <i>Expert Opinion on Biological Therapy</i> 2001 Vol. 1 pp. 629-639.
		Fiume L, et al. "Inhibition of hepatitis viral replication by vidarabine monophosphate conjugated with lactasaminated serum albumin. <i>Lancet</i> 1988 Vol. 2 pp. 13-15.
		Fiume L, et al. "The pathogenesis of vacuoles produced in rat and mouse liver cells by a conjugate of adenine arabinoside monophosphate with lactosaminated albumin. <i>J Hepatology</i> 1992 Vol. 15 pp. 314-322.
		Furumoto K, et al. "Biliary excretion of polystyrene microspheres depends on the type of receptor-mediated uptake in rat liver. <i>Biochimica et Biophysica Acta</i> 2001 Vol. 1526 pp. 221-226.
		Goldberg J, et al. "Erythropoietin mimetics derived from solution phase combinatorial libraries. <i>J Amer Chem Soc</i> 2002 Vol. 124 pp. 544-555.
		Groman EV, et al. "Arabinogalactan for hepatic drug delivery. <i>Bioconj Chem</i> 1994 Vol. 5 pp. 547-556.
		High KA. "Gene transfer as an approach to treating hemophilia. <i>Circulation Research</i> 2001 Vol. 88 pp. 137-144.
		Koide A, et al. "The fibronectin type III domain as a scaffold for novel binding proteins. <i>Journal of Molecular Biology</i> 1998 Vol. 284 pp. 1141-1151.
		Lee YC, et al. "Binding of synthetic oligosaccharides to the hepatic gal/GalNAc lectin. <i>J Biol Chem</i> 1983 Vol. 258 pp. 199-202.
		Meiher DKF, et al. "Drug targeting systems for antiviral agents: options and limitations. <i>Antiviral Research</i> 1992 Vol. 18 pp. 215-258.
		Nord K, et al. "Binding proteins selected from combinatorial libraries of an alpha-helical bacterial receptor domain. <i>Nature Biotechnology</i> 1997 Vol. 15 pp. 772-777.
		Nord K, et al. "A combinatorial library of an alpha-helical bacterial receptor domain.

		<i>Protein Engineering</i> 1995 Vol. 8 pp. 601-608.
		Okuno K, et al. "Hepatic immunopotentiality by galactose-entrapped liposomal IL-2 compound in the treatment of liver metastases. <i>Surg Today</i> 1998 Vol. 28 pp. 64-69.-
		Rensen PC, et al. "Determination of the upper size limit for uptake and processing of ligands by the asialoglycoprotein receptor on hepatocytes <i>in vitro</i> and <i>in vivo</i> . <i>Journal of Biological Chemistry</i> 2001 Vol. 276 pp. 37577-37584.
		Rogers JC, et al. "Hepatic uptake of proteins coupled to fetuin glycoprotein. <i>Biochem Biophys Res Comm</i> 1971 Vol. 45 pp. 622-629.
		Schlepper-Schafer J, et al. "Endocytosis via galactose receptors <i>in vivo</i> . Ligand size directs uptake by hepatocytes and/or liver macrophages. <i>Experimental Cell Research</i> 1986 Vol. 165 pp. 494-506.
		Severin E, et al. "Flow cytometric analysis of mouse hepatocyte ploidy. II. The development of polyploidy pattern in four mice strains with different life spans. <i>Cell & Tissue Research</i> 1984 Vol. 238 pp. 649-652.
		Shimada K, et al. "Biodistribution of liposomes containing synthetic galactose-terminated diacylglycerol-poly(ethylene)glycols. <i>Biochim Biophys Acta</i> 1997 Vol. 1326 pp. 329-341.
		Sokoloff AV, et al. "Specific recognition of protein carboxy-terminal sequences by natural IgM antibodies in normal serum. <i>Molecular Therapy</i> 2001 Vol. 3 pp. 821-830.
		Sokoloff AV, et al. "The interactions of peptides with the innate immune system studied with use of T7 phage peptide display. <i>Molecular Therapy</i> 2000 Vol. 2 pp. 131-139.
		Sokoloff AV, et al. "A new peptide ligand that targets particles and heterologous proteins to hepatocytes <i>in vivo</i> ." <i>Molecular Therapy</i> 2003 Vol. 8 No. 6 pp. 867-872.
		Steven AC, et al. "Molecular substructure of a viral receptor-recognition protein. The gp17 tail-fiber of bacteriophage T7. <i>Journal of Molecular Biology</i> 1988 Vol. 200 pp. 351-365.
		Studier FW "The genetics and physiology of bacteriophage T7. <i>Virology</i> 1969 Vol. 39 pp. 562-574.
		Tomlinson E "Theory and practice of site-specific drug delivery. <i>Advance Drug Delivery Reviews</i> 1987 Vol. 1 pp. 87-98.
		van Berkel JC, et al. "The effect of a water-soluble tris-galactoside-terminated cholesterol derivative on the fate of low density lipoproteins and liposomes. <i>J Biol Chem</i> 1985 Vol. 260 pp. 2694-2699.
		Vyas SP, et al. "Endogenous carriers and ligands in non-immunogenic site-specific drug delivery. <i>Advanced Drug Delivery Reviews</i> 2000 Vol. 43 pp. 101-164.
		Weglarz TC, et al. "Hepatocyte transplantation into diseased mouse liver. Kinetics of parenchymal repopulation and identification of the proliferative capacity of tetraploid and octaploid hepatocytes. <i>American Journal of Pathology</i> 2000 Vol. 157 pp. 1963-1974.
		Wu J, et al. "Targeting hepatocytes for drug and gene delivery pp. emerging novel approaches and applications. <i>Frontiers in Bioscience</i> 2002 Vol. 7 pp. 717-725.

Examiner:	Date Considered:
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